

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner—(1) Board of Tea Experts.*

(i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(2) *Science Board to the Food and Drug Administration.*

(i) Date established: June 26, 1992.

(ii) Function: The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

(b) *Center for Biologics Evaluation and Research—*

(1) *Allergenic Products Advisory Committee.*

(i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

(2) *Biological Response Modifiers Advisory Committee.*

(i) Date established: October 28, 1988.

(ii) Function: Reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

(3) *Blood Products Advisory Committee.*

(i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(4) [Reserved]

(5) *Vaccines and Related Biological Products Advisory Committee.*

(i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(c) *Center for Drug Evaluation and Research—(1) Anesthetic and Life Support Drugs Advisory Committee.*

(i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anesthesiology and surgery.

(2) *Anti-Infective Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

(3) *Antiviral Drugs Advisory Committee.*

(i) Date established: February 15, 1989.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

(4) *Arthritis Advisory Committee.*

(i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

(5) *Cardiovascular and Renal Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human

drugs for use in cardiovascular and renal disorders.

(6) *Dermatologic and Ophthalmic Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

(7) *Drug Abuse Advisory Committee.*

(i) Date established: May 31, 1978.

(ii) Function: Advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

(8) *Endocrinologic and Metabolic Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

(9) *Fertility and Maternal Health Drugs Advisory Committee.*

(i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics and gynecology.

(10) *Gastrointestinal Drugs Advisory Committee.*

(i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

(11) *Oncologic Drugs Advisory Committee.*

(i) Date established: September 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

(12) *Peripheral and Central Nervous System Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of

marketed and investigational human drugs for use in neurological disease.

(13) *Psychopharmacologic Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

(14) *Pulmonary-Allergy Drugs Advisory Committee.*

(i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(15) *Medical Imaging Drugs Advisory Committee.*

(i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

(16) *Generic Drugs Advisory Committee—*

(i) Date established: January 22, 1990.

(ii) Function: Gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases and makes appropriate recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, the Commissioner of Food and Drugs, and the Director of the Center for Drug Evaluation and Research. The committee may also review agency-sponsored intramural and extramural biomedical research programs in support of FDA's generic drugs regulatory responsibilities.

(17) *Nonprescription Drugs Advisory Committee.*

(i) Date established: August 27, 1991.

(ii) Functions: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the

treatment of a broad spectrum of human symptoms and diseases.

(d) *Center for Devices and Radiological Health—*

(1) *Medical Devices Advisory Committee.*

(i) *Date established:* October 27, 1990.

(ii) *Function:* Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) *Date established:* May 17, 1987.

(ii) *Function:* Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(3) *Technical Electronic Product Radiation Safety Standards Committee.*

(i) *Date established:* October 18, 1968.

(ii) *Function:* Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(4) *National Mammography Quality Assurance Advisory Committee.*

(i) *Date established:* July 6, 1993.

(ii) *Function:* Advises on developing appropriate quality standards and regulations for the use of mammography facilities.

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) *Date established:* June 2, 1973.

(2) *Function:* Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

(f) *Center for Veterinary Medicine—Veterinary Medicine Advisory Committee.*

(1) *Date established:* April 24, 1984.

(2) *Function:* Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

(g) *Center for Food Safety and Applied Nutrition—Food Advisory Committee.* (1)

Date established: December 15, 1991.

(2) *Function:* The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

[54 FR 9036, Mar. 3, 1989, as amended at 54 FR 11698, Mar. 22, 1989; 55 FR 5838, Feb. 20, 1990; 55 FR 7316, Mar. 1, 1990; 55 FR 51282, Dec. 13, 1990; 56 FR 26613, June 10, 1991; 56 FR 48103, Sept. 24, 1991; 57 FR 8064, Mar. 6, 1992; 57 FR 14350, Apr. 20, 1992; 57 FR 35461, Aug. 10, 1992; 58 FR 17096, Apr. 1, 1993; 58 FR 41635, Aug. 5, 1993; 58 FR 62521, Nov. 29, 1993; 60 FR 9297, Feb. 27, 1995]

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or